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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,961	11/25/2003	Marianne Ulrich Jorgensen	6297.204-US	8713

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,961	JORGENSEN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.e.e

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and15-17drawn to an isolated polypeptide comprising at least bone Kunitz domain that comprises an amino acid sequence according to the formula of claim 1 (SEQ ID NO 2), wherein the amino acid sequence is at least about 80% identical to the sequence of residues 5-55 of SEQ ID NO: 1, wherein the amino acid sequence of said polypeptide is characterized by one or more of the conditions of claim 2 and 3., wherein said polypeptide of claim 3 detectably inhibits the activity of at least one of the proteases selected from the group consisting of chymotrypsin, elastase, cathepsin G, proteinase 3, plasmin, plasma kallikrein, glandular kallikrein and trypsin ; and composition comprising the said polypeptide; classified in class 530, subclass 350, 300; class 514, subclass 2; Class 435, subclass 183+.

The claims in group I contain reference to patentably distinct and/or independent peptides, see claim 1 for each Xaa numbers. Should group I be elected, applicant is required to select one residue to define the sequence; or select one sequence by SEQ ID NO: (e.g., claim 11). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Additionally, applicant is required to select one protease from the group of protease claimed in claim 4.

II. Claims 12-14 drawn to an isolated nucleic acid encoding the polypeptide of claim 3, a vector comprising said nucleotide, a host cell transformed with said nucleotide; classified in class 536, subclass 23.1, 23.5; class 435, subclass 69.1, 320.1, 252.3, 325.

The claims in group II contains reference to patentably distinct and/or independent peptides, see claim 3 for each Xaa numbers. Should group II be

elected, applicant is required to select one residue to define the sequence. Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide.

III. Claims 18-20, drawn to a method for inducing, promoting, and/or enhancing at least one physiological response associated with the treatment or prevention of systemic inflammatory response syndrome, acute pancreatitis, shock syndrome, hyperfibrinolytic hemorrhage, or myocardial infarction or for preventing, blood loss in a subject comprising administering the composition of claim 15;classified in class 530, subclass 350, 300; class 514, subclass 2, 44.
Should group I be elected, applicant is required to select one residue to define the sequence; or select one sequence by SEQ ID NO: (e.g., claim 11). Any change of amino acid residue at any one or more positions in the sequence is considered, absent factual data to the contrary, a distinct peptide. Additionally, applicant is required to select one protease from the group of protease claimed in claim 4.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of invention I and polynucleotide of invention II are different products. They differ with respect to their structures, physical, chemical and biological properties and function. Therefore, the inventions are patentably distinct.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the claimed polypeptide of invention I can be used in a materially different process such as in the production of antibodies specific for the protein. Therefore, the inventions are patentably distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP ' 806.04, MPEP ' 808.01). In the instant case the polynucleotide of group II is a separate and distinct chemical entity from the polypeptide of group III and is not used in the method of group III. The polynucleotide of group II has different functions from the polypeptides of III. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
July 1, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER